INTERNATIONAL STANDARD

ISO 8655-1

First edition
2002-09-15

Piston-operated volumetric apparatus —

Part 1: Terminology, general requirements and user recommendations

Appareils volumétriques à piston —

Partie 1: Définitions, exigences générales et recommandations pour l'utilisateur

Reference number
ISO 8655-1:2002(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

Contents

Page

Annex

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 8655 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 8655-1 was prepared by Technical Committee ISO/TC 48, *Laboratory glassware and related apparatus*, Subcommittee SC 1, *Volumetric instruments*.

ISO 8655 consists of the following parts, under the general title *Piston-operated volumetric apparatus*:

— *Part 1: Terminology, general requirements and user recommendations*

— *Part 2: Piston pipettes*

— *Part 3: Piston burettes*

— *Part 4: Dilutors*

— *Part 5: Dispensers*

— *Part 6: Gravimetric methods for the determination of measurement error*

The following part is under preparation:

— *Part 7: Non-gravimetric methods for the determination of measurement error*

Annex A forms a normative part of this part of ISO 8655.

Introduction

ISO 8655 addresses the needs of:

— suppliers, as a basis for quality control including, where appropriate, the issuance of supplier's declarations;

— test houses and other bodies, as a basis for independent certification;

— users of the equipment, to enable routine checking of accuracy.

The tests specified should be carried out by trained personnel.

Piston-operated volumetric apparatus —

Part 1:
Terminology, general requirements and user recommendations

1 Scope

This part of ISO 8655 specifies the general requirements for piston-operated volumetric apparatus. It is applicable to piston pipettes, piston burettes, dilutors and dispensers. It furthermore defines terms for the use of piston-operated volumetric apparatus and gives user recommendations.

ISO 8655 is not applicable to medical products intended for use on human beings, e.g. for medical syringes.

NOTE For metrological requirements, maximum permissible errors, requirements for marking and information to be provided for users for piston-operated volumetric apparatus, see ISO 8655-2 for piston pipettes, see ISO 8655-3 for piston burettes, see ISO 8655-4 for dilutors and see ISO 8655-5 for dispensers. Conformity testing (type evaluation) of piston-operated volumetric apparatus is given in ISO 8655-3. Alternative test methods such as photometric and titrimetric methods will be the subject of a future Part 7 to ISO 8655. For all other tests (e.g. quality assurance by the supplier, analytical and measuring equipment quality assurance by the user) see ISO 8655-6 or alternative test methods.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 8655. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 8655 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8655-2:2002, *Piston-operated volumetric apparatus — Part 2: Piston pipettes*

ISO 8655-3:2002, *Piston-operated volumetric apparatus — Part 3: Piston burettes*

ISO 8655-4:2002, *Piston-operated volumetric apparatus — Part 4: Dilutors*

ISO 8655-5:2002, *Piston-operated volumetric apparatus — Part 5: Dispensers*

ISO 8655-6:2002, *Piston-operated volumetric apparatus — Part 6: Gravimetric methods for the determination of measurement error*

IEC 60073, *Basic and safety principles for man-machine interface, marking and identification — Coding principles for indication devices and actuators*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements*

IEC 61326-1, *Electrical equipment for measurement, control and laboratory use — EMC requirements*

3 Terms and definitions

For the purposes of this part of ISO 8655, the following terms and definitions apply.

3.1 Metrological terms

3.1.1
maximum permissible error
upper or lower permitted extreme value for the deviation of the dispensed volume from the nominal volume (3.1.5) or selected volume (3.1.6) of a piston-operated volumetric apparatus

NOTE 1 A general definition for maximum permissible error is given in the VIM.

NOTE 2 The maximum permissible errors of piston-operated volumetric apparatus are specified in ISO 8655-2 to ISO 8655-5. Conformity testing for observance of maximum permissible errors is performed gravimetrically in accordance with ISO 8655-6.

3.1.2
systematic error
⟨piston-operated volumetric apparatus⟩ difference between the dispensed volume and the nominal volume or selected volume of the piston-operated volumetric apparatus

NOTE 1 General definitions for systematic error are given in the VIM and ISO 3534-1.

NOTE 2 For conformity testing in accordance with ISO 8655-6, the systematic error is ascertained by taking the mean of 10 measurements.

3.1.3
random error
⟨piston-operated volumetric apparatus⟩ scatter of the dispensed volumes around the mean of the dispensed volumes

NOTE 1 General definitions for random error are given in the VIM and ISO 3534-1.

NOTE 2 For conformity testing in accordance with ISO 8655-6, the random error is ascertained by taking the repeatability standard deviation of 10 measurements.

3.1.4
uncertainty of measurement
⟨volume dispensed by a piston-operated apparatus⟩ parameter, associated with the dispensed volume, that characterizes the dispersion of the volumes that could reasonably be attributed to the dispensed volume

NOTE 1 Adapted from the VIM.

NOTE 2 The uncertainty of measurement comprises portions of the systematic and random error of measurement. The calculation of the uncertainty of measurement can be performed with the equation given in annex B of ISO 8655-6:2002.

3.1.5
nominal volume
⟨piston-operated volumetric apparatus⟩ volume specified by the manufacturer and used for identification and for indication of the measuring range

NOTE For specific piston-operated volumetric apparatus such as variable-volume piston pipettes and multi-channel piston pipettes, this definition is further qualified in the applicable parts of ISO 8655.

3.1.6
selected volume
⟨variable-volume volumetric apparatus⟩ volume set by the user, in order to dispense a volume chosen from the useful volume range (3.1.7) of a variable-volume piston-operated volumetric apparatus

NOTE For a fixed-volume piston-operated volumetric apparatus, the selected volume is equal to the nominal volume.

3.1.7
useful volume range
that part of the nominal volume which allows dispensing under observance of the maximum permissible errors as specified in the applicable part of ISO 8655

NOTE 1 The upper limit of the useful volume range is always the nominal volume. The lower limit is 10 % of the nominal volume if not otherwise specified by the supplier.

NOTE 2 For piston-operated burettes, provision may be made in the design for the burette to be recharged automatically (involving more than one stroke of the piston) before the required volume has been dispensed.

3.1.8
dead air volume
⟨piston-operated pipettes with air interface⟩ air volume between the lower part of the piston and the surface of the liquid

3.1.9
dead liquid volume
⟨positive displacement pipettes, burettes, dilutors and dispensers⟩ amount of liquid which does not belong to the dispensed volume and which is contained during operation in aspiration or expelling tubes, valves and within the cylinder

3.1.10
adjustment
⟨piston-operated volumetric apparatus⟩ manufacture of an apparatus within appropriate tolerances, or the supplier's setting of the apparatus, ensuring the metrological performance, as specified in the applicable part of ISO 8655, for a reference temperature of 20 °C

3.1.11
user adjustment
⟨piston-operated pipette⟩ adjustment employing only the means at the disposal of the user

NOTE 1 Adapted from the VIM.

NOTE 2 Adjustment requires operations which modify the apparatus for subsequent measurements.

3.1.12
calibration
⟨piston-operated volumetric apparatus⟩ set of operations that establish the relationship between the dispensed volume and the corresponding nominal or selected volume of the apparatus

NOTE 1 Adapted from the VIM.

NOTE 2 The result of a calibration permits the determination of correction values of the dispensed volume and its associated expanded uncertainty, e.g. following an adjustment or user adjustment.

NOTE 3 The result of a calibration may be recorded in a document called a calibration certificate or a calibration report.

NOTE 4 Calibration requires no operation which permanently modifies the apparatus.

3.2 Terms related to testing

3.2.1
conformity testing
⟨piston-operated volumetric apparatus⟩ systematic examination to determine whether the requirements specified in this International Standard, especially in a metrological sense, are fulfilled

NOTE 1 Adapted from ISO/IEC Guide 2.

NOTE 2 The corresponding test methods are specified in the applicable part of ISO 8655.

3.2.2
type testing
conformity testing on the basis of one or more specimens of a product representative of the production

3.2.3
supplier
party that is responsible for the piston-operated volumetric apparatus and is able to ensure that quality assurance is exercised

NOTE This definition may apply to manufacturers, distributors, importers, assemblers, service organizations, etc.

3.2.4
supplier's declaration
document by which a supplier gives written assurance that a piston-operated volumetric apparatus conforms to the requirements of this International Standard

NOTE The supplier's declaration can be issued after conformity testing.

3.2.5
certificate of conformity
document issued under the rules of a certification system, providing confidence that conformity testing has been performed and that the piston-operated volumetric apparatus fulfills the requirements specified in this International Standard

NOTE 1 Adapted from ISO/IEC Guide 2.

NOTE 2 Certificates of conformity for piston-operated volumetric apparatus are always related to the entire system including metrologically relevant accessories. For this reason, certificates of conformity for pipette tips and for burette change-over units indicate combinations of piston-operated volumetric apparatus and accessories for which the certificate applies.

3.2.6
calibration certificate
document issued after the calibration of a piston-operated volumetric apparatus, reporting the result of calibration

4 Types of piston-operated volumetric apparatus

4.1 General

Piston-operated volumetric apparatus includes a range of devices intended to aspirate or deliver specific volumes of liquids; they may be manually or automatically operated and are controlled by mechanical, electro-mechanical or electronic means.

4.2 Piston pipettes

Piston-operated pipettes are used to pick up and deliver liquids. Single-channel piston pipettes have only one piston/cylinder assembly. Multi-channel piston pipettes have a piston/cylinder assembly for each channel; the same volume of liquid can be delivered into several receptacles simultaneously (for example the wells of a microtitre plate). Piston-operated pipettes may be factory-preset to deliver a given volume, or may have user-selectable volumes within a useful volume range.

Piston-operated pipettes may be of the positive displacement or air-displacement type (see ISO 8655-2).

4.3 Piston burettes

Piston burettes are designed to deliver liquid progressively until the volume delivered is sufficient to satisfy external (usually analytical) criteria such as change of colour, pH, conductivity or polarization. The volume delivered may be read from a display or recorded from the apparatus by other means (see ISO 8655-3).

4.4 Dilutors

Dilutors are used to deliver mixtures of liquids of defined volumetric proportions. The intended volumes of sample and dilution fluid, chosen to provide a combined volume of the required dilution ratio, are user selected prior to the uptake and delivery of the liquids. According to ISO 8655-4, dilutors may be constructed with or without valves, and may be of fixed or variable volume.

4.5 Dispensers

Dispensers are used for the repetitive delivery (dispensing) of a measured volume of liquid. Single-stroke dispensers provide a single delivery from each filling stroke. Multiple delivery dispensers or ratchet-based systems provide multiple deliveries from each filling stroke.

5 General requirements and testing

Piston-operated volumetric apparatus shall conform to the appropriate requirements of the following specifications.

— Electrical and general safety requirements, in accordance with IEC 61010-1.

— Electromagnetic compatibility requirements, in accordance with IEC 61326-1.

— The marking and layout of electronic displays, meters and controls in accordance with IEC 60073.

6 Product information

6.1 User information

Instructions for use shall be packaged with each piston-operated volumetric apparatus. The instructions shall include at least the following user information.

a) The contents of the apparatus package shall be listed including accessories. If the piston-operated volumetric apparatus cannot properly be used as delivered, detailed information concerning the required additional parts and a recommendation as to where to acquire them shall be included.

b) Detailed information on the sterilization of the piston-operated volumetric apparatus or its parts, including acceptable sterilization media (such as steam, hot air, ethylene oxide), sterilization temperature (such as 100 °C, 121 °C), and limiting conditions (e.g. maximum recommended pressure for autoclaving) shall be given. It shall be made clear whether and to what extent the piston-operated volumetric apparatus shall be dismantled for sterilization.

   If no such information is included in the user information, then the piston-operated volumetric apparatus shall be understood not to be sterilizable.

c) Instructions for care, cleaning and maintenance of the piston-operated volumetric apparatus shall be given.

d) Further minimum information for individual apparatus types (see clause 4) as specified in the applicable parts of ISO 8655 shall be given.

e) The temperature range in which the piston-operated volumetric apparatus can be used shall be given.

6.2 Decontamination

The supplier shall, upon request, indicate how the piston-operated volumetric apparatus can be dismantled for further decontamination in case it is used in conjunction with radioactive, or chemically or microbiologically hazardous substances. The decontamination is placed under the responsibility of the user. Piston-operated volumetric apparatus shall not be sent to third parties if it is not decontaminated.

6.3 Chemical resistance

The supplier shall, upon request, provide information regarding the chemical resistance of the piston-operated volumetric apparatus against organic and inorganic solutions and solvents.

7 Factors affecting choice of piston-operated volumetric apparatus

7.1 Interaction with liquids

The range of applications of piston-operated volumetric apparatus is determined, among other factors, by the workmanship and choice of the materials from which they are made. The effect of the liquid to be delivered can, on the one hand, affect the metrological performance of the apparatus. On the other hand, the apparatus can, by the transfer of substances or trace elements, or through catalytic effects, affect the characteristics of the delivered liquid, without measurably altering the metrological performance of the apparatus.

The user should verify that the piston-operated volumetric apparatus is resistant to the liquid that it is intended to measure, and that no contamination of the liquid takes place. This can be accomplished, for example, by referring to resistance tables or, if necessary, by undertaking tests on the apparatus and the liquid in question. Refer also to 6.1 e), 6.2 and 6.3.

7.2 Use of piston pipettes with air interface

In order to achieve the most accurate measurements, the user should note and observe the instructions for use provided by the manufacturer. Special care shall be taken to avoid liquid being aspirated into the interior workings of the pipette.

Annex B in ISO 8655-2:2002 provides comprehensive information on possible sources of error and how to avoid them.

Tips made of plastic for piston pipettes with air interface are designed for single use. They should not be cleaned for reuse as their metrological characteristics can no longer be reliable.

7.3 Testing by the user

Users should establish acceptable maximum permissible systematic and random errors based on the field of use and the accuracy requirements placed on the piston-operated volumetric apparatus.

The conformity to the acceptable maximum permissible errors shall be tested by the users at regular intervals as part of their test equipment monitoring or analytical quality control routines, for example every three months but at least once a year. Other time intervals may be specified by the users depending upon

— frequency of use,

— number of users of the piston-operated volumetric apparatus,

— aggressive nature of the liquid to be delivered, and

— acceptable maximum permissible errors established by the user.

Testing can be done gravimetrically in accordance with ISO 8655-6or by other methods.

NOTE Alternative test methods such as photometric and titrimetric methods will be specified in the future Part 7 to ISO 8655.

When testing following maintenance or repair, the maximum permissible errors established in the applicable part of ISO 8655 apply.

8 Marking

Marking of the individual piston-operated volumetric apparatus shall be done in accordance with ISO 8655-2, ISO 8655-3, ISO 8655-4 or ISO 8655-5, as appropriate.

Annex A
(normative)

List of equivalent terms

NOTE In addition to terms used in the two official ISO languages, this annex gives the equivalent terms in German and Finnish; these are published under the responsibility of the member bodies for Germany (DIN) and for Finland (SFS). However, only the terms given in the official languages can be considered as ISO terms.

English	French	German	Finnish
Maximum permissible error [a]	Erreur maximale tolérée	Fehlergrenzen	Suurin sallittu virhe
Error (of indication) of a measuring instrument [a]	Erreur (de mesure)	Messabweichung	Virhe
Accuracy [a b c]	Exactitude	Genauigkeit	Tarkkuus
Trueness [b c]	Justesse	Richtigkeit	Oikeellisuus
Precision [b c]	Fidélité	Präzision	Toistettavuus
Systematic error [a b]	Erreur systématique	Systematische Messabweichung	Järjestelmällinen virhe
Bias [a c]	Erreur systématique	Systematische Messabweichung	Poikkeama
Random error [a b]	Erreur aléatoire	Zufällige Messabweichung	Satunnaisvirhe
Repeatibility standard deviation [b c]	Écart-type de répétabilité	Wiederhol-Standardabweichung	Toistettava keskihajonta
Uncertainty of measurement [a b d]	Incertitude de mesure	Messunsicherheit	Mittauksen epävarmuus
Adjustment [a d]	Ajustage	Justierung	Säätö
Calibration [a d]	Étalonnage	Kalibrierung	Kalibrointi
Verification [e]	Vérification	Eichung	Varmistus
Nominal volume	Volume nominal	Nennvolumen	Nimellistilavuus
Useful volume range	Plage de volume	Nutzvolumen	Käytettävissä oleva tilavuusalue
Carry-over	Volume de liquide résiduel	Verschleppung	Carry over
Supplier	Fournisseur	Anbieter	

[a] The term is defined in the VIM.

[b] The term is defined in ISO 3534-1.

[c] The term is defined in ISO 5725-1.

[d] The term is defined in ISO 10012-1.

[e] The term is defined in OIML R 76-1.

Bibliography

[1] ISO 3534-1, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms*

[2] ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

[3] ISO 10012-1, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment*

[4] ISO/IEC Guide 2, *Standardization and related activities — General vocabulary*

[5] *International vocabulary of basic and general terms in metrology* (VIM), BIPM, IEC, IFCC, ISO, INPAC, INPAP and OIML, 1993

[6] OIML R 76-1:1992, *Non-automatic weighing instruments — Part 1: Metrological and technical requirements — Tests*

ICS 01.040.17; 17.060

Price based on 9 pages